Supreme Court, U.S.
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No. 04-476

IN THE

Supreme Court of the United States

UNIVERSITY OF ROCHESTER,

Petitioner,

v.

G.D. SEARLE & CO., INC., MONSANTO CO., PHARMACIA CORPORATION, AND PFIZER INC.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENTS' BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether 35 U.S.C. § 112, which provides that a patent specification must provide a written description of both "the invention" and "the manner and process of making and using it," requires that the specification describe the invention as well as how one skilled in the art can make and use it.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondents G.D. Searle & Co., Inc. (now G.D. Searle LLC), Monsanto Company (now Pharmacia Corporation), Pharmacia Corporation, and Pfizer Inc. (collectively, "Pfizer") state that, pursuant to a transaction on April 16, 2003, Pfizer Inc. directly or indirectly owns all of the stock of Pharmacia Corporation and G.D. Searle LLC. Pfizer Inc. has no parent and no publicly held company owns 10% or more of Pfizer Inc.'s stock.

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RESPONDENTS' BRIEF IN OPPOSITION

This case involves a patent that purports to claim a method of selectively inhibiting an enzyme, but that does not disclose any means of doing so. Rather, as both the district court, Pet. App. 32a-33a, and court of appeals, Pet. App. 29a, found, the patent instructs the practitioner to find, by trial and error, a compound that selectively inhibits the enzyme in question, and to administer such an unspecified compound to a person in need of treatment. Indeed, as the courts below found, Pet. App. 19a-20a, 46a, 54a, the putative "inventors" do not claim to have known of any compound that performed the claimed function at the time of the patent's filing, or even whether such a compound then existed. Accordingly, the district court held, Pet. App. 55a-56a, 67a-68a, that the patent in question is invalid, both because it does not provide "a written description of the invention" and because it does not "enable" one skilled in the art to make and use it; and the court below affirmed, stating both that the patent lacked the "written description of the invention" required by 35 U.S.C. § 112 and that the patent quite arguably "failed to satisfy the requirements of section 102(f)" that it claim subject matter actually invented by the patentee. Pet. App. 28a, 29a-30a n.10.

Notwithstanding these multiple alternative grounds for decision and the clear invalidity of the patent in issue, the petition asks this Court to use this case as a vehicle for deciding whether 35 U.S.C. § 112 contains a "written description" requirement that is independent of the statute's so-called "enablement" requirement. The petition does so even though the district court found that the patent in issue does not enable the claimed invention, and even though the judges who voted for rehearing en banc below agreed that the question presented is a purely academic one, since they agreed that this patent does not enable, and since they recognized that the question presented has never arisen in an actual case where enablement exists. Indeed, those judges argued that, far from being an important and recurring issue

of federal patent law warranting this Court's review, the entire issue is legally "superfluous" and unlikely to arise in real litigation in a context that could affect the outcome of a case. Pet. App. 88a-89a.

Such a hypothetical and speculative issue is plainly not worthy of this Court's review. There is no alleged conflict with this Court's precedents and no conflict in judgments of the Federal Circuit — let alone any inter-circuit division of authority — but rather only persistent dissents by a few individual judges of the Federal Circuit from an unbroken line of cases recognizing and applying the independent written description requirement. As noted, however, even these judges have conceded that the application of this independent written description requirement has never made, and is unlikely to make, a difference in the outcome of any case; and the United States Patent and Trademark Office ("PTO") has in fact issued guidelines, after notice and comment, that expressly endorse the Federal Circuit's precedents on this question, and reject the position urged in the petition. Finally, as noted above, this case presents a particularly inappropriate vehicle for deciding the question presented, because the decisions below, as well as the three primary dissenters from the denial of rehearing en banc, recognized independent grounds for the judgment below regardless of how the independent written description issue would be decided. Pet. App. 23a, 29a-30a n.10, 88a.

In any event, the decision below is plainly correct. The plain language of section 112 expressly requires that a patent specification disclose a written description "of the invention" as well as a description of how to make and use that invention. The PTO has so read and administered the statute. And none of petitioner's extratextual policy arguments against applying the statute according to its terms and the PTO's construction of it have any merit. There is thus no warrant for this Court's review.

STATEMENT OF THE CASE

1. The human body produces certain enzymes called cyclooxygenases. These enzymes contribute to pain and inflammation at the sites of injuries. Non-steroidal anti-inflammatory drugs like aspirin operate by inhibiting cyclooxygenases, thereby relieving the pain and inflammation that they can cause.

Scientists have discovered that there are two different types of cyclooxygenases in the human body, only one of which is primarily associated with contributing to pain and inflammation at injury sites. COX-2 is believed to be primarily responsible for the pain and inflammation previously known to be associated with cyclooxygenases generally; the other cyclooxygenase, COX-1, occurs in the gastrointestinal tract, where it assists in the protection of the stomach lining. Aspirin and other traditional non-steroidal anti-inflammatory drugs inhibit cyclooxygenases generally, without distinguishing between COX-1 and COX-2.

In the 1990s, scientists employed by petitioner the University of Rochester (the "University") developed a method for screening non-steroidal anti-inflammatory drugs to determine their relative impact on the COX-1 and COX-2 enzymes. They applied for, and received, a patent for these methods in 1998. That patent is not at issue in this case.

In 2000, the University's scientists also obtained, a separate patent, U.S. Patent No. 6,048,850, that purports to disclose a method of selectively inhibiting COX-2. Each claim in the '850 patent involves a method of "administering a non-steroidal compound that selectively inhibits the [COX-2] gene product." Federal Circuit Joint Appendix ("JA") A0147(71:35-72:57). The patent does not, however, disclose any such compound, nor how to make such a compound. Rather, the '850 patent merely discloses a screening method to determine whether a compound acts selectively on COX-2.

Specifically, the '850 patent discloses "cells that express [COX-1] or [COX-2] exclusively," an "assay" to determine the activity of the COX-1 and COX-2 genes, and an *in vitro* assay "to evaluate" the ability "of a compound to selectively inhibit [COX-2]" using these cell lines. JA A0113(3:46-47, 56-57), A0123(24:51-58, 60-62). In other words, the patent contains no "suggestion that the inventors had identified so much as one compound that would be suitable for use in practicing the claimed invention," and no guarantee that the screening method described in the '850 patent will "inherently produce" any such compound. Pet. App. 46a, 54a n.7.

2. On the same day that the '850 patent issued, the University sued respondents for allegedly infringing it. The University's lawsuit alleged that certain COX-2-specific inhibitors sold by respondents, Celebrex® and Bextra®, infringed the '850 patent. Respondents moved for summary judgment on the ground that the '850 patent was invalid for failing to meet the requirements imposed by 35 U.S.C. § 112, the provision of the Patent Law which provides:

> The specification [of a patent] shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In response, the University did not argue that the '850 patent actually disclosed any COX-2 inhibitors. Rather, the University submitted expert declarations describing general biomedical research methodologies used to identify new pharmaceutical compounds. None of the declarations stated that it was routine to create or find a COX-2-specific inhibitor of the sort alluded to in the patent. Instead, they asserted that it is routine for research-based pharmaceutical

companies to do research to try to invent new drugs, that "it would not have been uncommon . . . to undertake a drug discovery program," JA A1273 ¶ 26, that the patent "provides tools . . . for identifying non-steroidal compounds suitable for use in the claimed methods," JA A0343-44 ¶ 6, A0388 ¶ 13, that skilled artisans "would have been confident" that they could make cells needed to perform petitioner's screening assay, JA A1312-13 ¶ 43, and that skilled artisans could have performed a "rapid and routine assessment of test compounds as potential selective Cox-2 inhibitors." JA A1272 ¶ 24.

The district court granted summary judgment for respondents based on both the written description and enablement requirements of 35 U.S.C. § 112. The district court found that the '850 patent merely discloses "a wish or plan or first step for obtaining a desired result" rather than a patentable invention, and that "[t]he reader [of the patent] also learns that the patentee had not proceeded to do what was necessary to accomplish the desired end." Pet. App. 32a. The district court observed that "such an 'invention' is not really one at all." Pet. App. 32a.

The district court explained that the patent failed the written description requirement because it lacks "any suggestion that the inventors had identified so much as one compound that would be suitable for use in practicing the claimed invention." Pet. App. 46a. At best, the court found, the University's patent "simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work." Pet. App. 44a.

Turning to the enablement requirement, the district court found that the patent did not disclose "any suitable compound" to use in the claimed method, and did not "explain how one can discover such a compound," Pet. App. 64a, apart from "undue experimentation, with no assurance of success," Pet. App. 60a. While petitioner's experts stated that researchers could search for a suitable compound using

"'routine' methods," the court found that the patent "provides precious little guidance" for "selecting" or "narrowing the range of candidates." Pet. App. 62a. "Tellingly, . . . what plaintiff's experts[] do *not* say is that one of skill in the art would, from reading the patent, understand what compound or compounds — which, as the patent makes clear, are necessary to practice the claimed method — would be suitable, nor would one know how to find such a compound except through trial and error, which hardly suggests conception of a complete invention." Pet. App. 54a. The district court concluded that petitioner's expert declarations did not support enablement because they addressed "use and function of the screening assay, rather than . . . actually discovering a suitable compound." Pet. App. 65a n.12. Thus, "[a]t most, [the patent's] description will enable a person of ordinary skill in the art to *attempt to discover* how to practice the claimed invention." Pet. App. 67a.

3. A panel of the Federal Circuit affirmed. The panel reaffirmed that, under the text of section 112 and a long line of Federal Circuit precedents, there exists a requirement that a patent specification contain a written description of the invention, and that while this requirement is related to the enablement requirement, the two are distinct. Pet. App. 9a-20a.

The Federal Circuit panel observed that "[t]he 'written description' requirement serves a teaching function, as a *quid pro quo* in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" Pet. App. 12a. The panel concluded that the '850 patent fails that requirement because it "does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods — an essential element of every claim of that patent — and has not provided evidence that any such

compounds were otherwise within the knowledge of a person of ordinary skill in the art." Pet. App. 28a.

In addition, while concluding that it need not separately reach the enablement issue in light of its ruling on the written description requirement, Pet. App. 28a, the panel expressly held that "[t]he claimed methods . . . cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art." Pet. App. 23a. Moreover, the panel also observed (Pet. App. 30a n.10) that "[h]ere the patentee has done no more than invent a search method," and, accordingly, concluded that "it might appear that the patentee also failed to satisfy the requirements of section 102(f)," which precludes the issuance of a patent where the applicant "did not himself invent the subject matter sought to be patented."

4. By a 7-5 vote, the Federal Circuit denied rehearing en banc. Pet. App. 70a, 78a n.1. Several judges wrote separately. Only three of the dissenters expressed disagreement with the merits of the panel decision, and one dissenting judge wrote to express agreement with the panel.

Judge Lourie wrote an opinion concurring in the denial of an en banc hearing, Pet. App. 74a-78a, emphasizing that "there is and always has been a separate written description requirement in the patent law." Pet. App. 74a; *see also* Pet. App. 75a ("It has always been there."). Judge Lourie explained that, to the extent that the decisions directly addressing this issue are not as numerous, this stemmed from the fact that "[l]egal holdings arise when they do because litigants raise them and courts have to decide them," and some issues related to the written description requirement simply have not arisen until recently. Pet. App. 75a.

Judge Dyk also concurred in the denial of rehearing en banc. Pet. App. 122a. While Judge Dyk recognized the need for further development of "our existing written description jurisprudence," he found that "the question of whether 35

U.S.C § 112 contains a written description requirement (separate from the enablement requirement)" "is clear." *Id.* Judge Dyk also found that this case did not present a proper vehicle for further developing the Federal Circuit's written description jurisprudence, because "[i]n this particular case the failure to satisfy that requirement was not even a close case. The appellant simply did not invent, much less describe, what was claimed." Pet. App. 122a.

Judge Newman dissented from the denial of an en banc hearing. Pet. App. 71a-73a. While Judge Newman "fully share[d] Judge Lourie's understanding of the law" on the merits, and agreed that the panel's decision rested upon "well-established and heretofore unchallenged" precedents, she expressed concern about a disagreement within the Federal Circuit regarding aspects of the court's written description requirement. Pet. App. 71a. In particular, Judge Newman expressed concern about issues raised in the context of "[t]he new biology," including the question of whether "deposit [of a biological material] in a public depository" satisfies the written description requirement. Pet. App. 71a-72a. (This case, of course, does not involve any such deposit.)

Judge Rader wrote an opinion dissenting from the denial of en banc review, which was joined by Judges Gajarsa and Linn. Pet. App. 78a-92a. Judge Rader disagreed that section 112 contains a written description requirement independent of the enablement requirement. Moreover, Judge Rader expressed the view that the written description requirement applied by the panel is "superfluous" because it "rarely, if ever, happens" that "a patent can enable an invention that is not described by the specification." Pet. App. 88a; *see also* Pet. App. 90a (stating that "as a practical matter" this situation "never occurs"). He stated that "[n]o actual case presents th[at] hypothetical," and expressly concluded that this case is no exception, because the claimed invention "was not enabled" by the '850 patent. Pet. App. 88a. Judge Linn

also wrote a dissenting opinion joined by Judges Rader and Gajarsa, arguing that section 112 should not be read "to contain a separate written description requirement beyond enablement." Pet. App. 120a.

REASONS FOR DENYING THE PETITION

The petition for a writ of certiorari should be denied. There is no conflict alleged between the decision below on the question presented and any decision of this Court, any other court of appeals, or, for that matter, any other decision of the Federal Circuit. Moreover, while the petition emphasizes that several judges of the Federal Circuit have voiced their disagreement with the overwhelming majority of that court about whether 35 U.S.C. § 112 contains an independent written description requirement, even those dissenting judges acknowledged that there is no case in which an invention has been enabled but not properly described under Federal Circuit law. Accordingly, by their own argument, the issue of concern to the dissenting judges is entirely hypothetical and, accordingly, clearly not one that warrants the time and attention of this Court. Indeed, because both the district court and the dissenting judges here found that the '850 patent did not enable any invention, and because the panel found that this patent appeared also to fail the requirements of 35 U.S.C. § 102, this case would be a particularly poor vehicle for addressing the question presented. And, in all events, the decision below is correct on the merits, as recognized by an overwhelming majority of the Federal Circuit judges, and as confirmed by published guidelines of the United States Patent and Trademark Office. There is thus no warrant whatsoever for the petition.

I. THERE IS NO CONFLICT OR UNCERTAINTY IN JUDICIAL OR ADMINISTRATIVE JUDGMENT ABOUT WHETHER A WRITTEN DESCRIPTION REQUIREMENT DISTINCT FROM THE ENABLEMENT REQUIREMENT EXISTS.

The University's primary argument is that this Court should grant certiorari to resolve an alleged "deep schism" within the Federal Circuit regarding whether section 112 imposes a "written description" requirement that is distinct from the enablement requirement. Pet. 15. In fact, no division in judicial judgment exists that would warrant this Court's review.

1. The University does not even suggest that review is justified based upon any conflict with precedents of this Court. This Court has in fact indicated its agreement with the Federal Circuit on the question presented. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 724 (2002) (noting that section 112 requires that the "application must describe, enable, and set forth the best mode of carrying out the invention"); *see also Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34 (1822) (distinguishing enablement and description objects of the specification under analogous provision of predecessor statute).

Nor does the petition claim that review is warranted to resolve a conflict between the circuits. Although petitioner argues that "there can be no inter-circuit conflicts on this question," Pet. 12, the regional circuits can in fact decide substantive issues of patent law — such as the question presented in the petition — where, for example, they are raised in counterclaims. *See Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 834 (2002). But no other circuit has yet disagreed with the Federal Circuit about whether 35 U.S.C. § 112 imposes a written description requirement distinct from its enablement requirement.

Finally, petitioner does not show any genuine intra-circuit division of authority on the question raised in the petition. Despite its hyperbole about an alleged intractable division within the Federal Circuit on the question whether there is a written description requirement separate from the enablement requirement, there are no decisions of that court that are in conflict, or even in tension, with the holding in this case. On the contrary, petitioner acknowledges an unbroken line of cases spanning over thirty years uniformly affirming the existence of an independent written description requirement. Pet. 14. Indeed, as Judge Lourie explained, Pet. App. 9a-16a, the Federal Circuit, and before its creation, the Court of Customs and Patent Appeals, have consistently applied separate written description and enablement requirements for decades. *See, e.g.*, *Regents of Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560-64 (Fed. Cir. 1991); *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984); *In re Barker*, 559, F.2d 588, 593 (CCPA 1977); *In re Smith*, 481 F.2d 910, 914 (CCPA 1973); *In re DiLeone*, 436 F.2d 1404, 1405 (CCPA 1971); *In re Ruschig*, 379 F.2d 990, 995-96 (CCPA 1967).

2. In arguing that there is a "deep schism" in judicial opinion on the question presented, the University in fact relies solely on quotations from several separate opinions of individual judges on the Federal Circuit. Pet. 14-17. Those opinions include three by Judge Rader, the author of the principal dissent from denial of rehearing en banc below, *see* Pet. App. 78a-92a; *Moba, B.V. v. Diamond Automation*, 325 F.3d 1306, 1324 (Fed. Cir.) (Rader, J., concurring), *cert. denied*, 124 S. Ct. 464 (2003); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 977-78 (Fed. Cir. 2002) (Rader, J., dissenting), and two from other judges, one of whom did *not* join in dissenting from rehearing en banc below, *see Moba, B.V.*, 325 F.3d at 1327-28 (Bryson, J., concurring); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1361

(Fed. Cir. 2003) (Clevenger, J., dissenting). The petition thus presents no conflict in judgments of the Federal Circuit (let alone a true *inter*-circuit conflict), or even in dictum in opinions for that court, but rather relies solely on the persistently expressed, separate views of a small minority of judges on the Federal Circuit. This Court, of course, does not sit to review such minor debates arising in the natural and orderly course of the conduct of judicial business.

Indeed, this Court's intervention would be particularly inappropriate here. Judge Rader, the principal judge expressing those dissenting views in the Federal Circuit, has argued that the question presented is a purely academic one. According to Judge Rader, the resolution of this question has never affected the outcome of any case, including this one. On Judge Rader's view, the written description requirement imposed by the Federal Circuit is "superfluous" because "[n]o actual case" has involved or likely will involve a specification that satisfies the enablement requirement but fails the written description requirement. Pet. App. 88a. Judge Rader expressly included this case, noting that the University's invention "was not enabled." Pet. App. 88a. Not only has "no case ever presented" the question in the petition in a context where it could affect the outcome, but Judge Rader saw it as "unfathomable" that such a case could arise. Pet. App. 89a.

In other words, while Judges Rader, Gajarsa and Linn (the latter two of whom joined Judge Rader's discussion) disagree with the distinct written description requirement long-established by the Federal Circuit, even they have argued that their disagreement is a theoretical one with no practical significance to the outcome of any real cases. Thus, far from being an important or recurring issue warranting this Court's attention, the question of federal law discussed by the dissenters and presented by the petition is entirely academic and speculative and may never arise in a real case in a way that could affect the outcome. This

Court's precious time and resources are not properly wasted on such a question.

3. The University also suggests that the Federal Circuit jurisprudence recognizing an independent written description requirement is in conflict with the views of the Executive Branch. Pet. 19. It is not. In fact, the University ignores that the PTO has issued authoritative guidelines on this issue — after publication of proposed guidelines in the Federal Register and extensive public comment — that expressly endorse the view of the Federal Circuit.

In 2001, the PTO issued *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement*, 66 Fed. Reg. 1099 (Jan. 5, 2001). The Guidelines endorse a written description requirement "separate and distinct from the enablement requirement" that can be satisfied only by "describ[ing] the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *Id.* at 1104; *see also id.* at 1100 ("Although the two concepts are entwined, they are distinct and each is evaluated under separate legal criteria."). In particular, the Guidelines provide that the written description requirement is not satisfied "if the knowledge and level of skill in the art would not permit one skilled in the art to *immediately envisage* the product claimed from the disclosed process." *Id.* at 1105 (emphasis added). Moreover, the PTO expressly stated its belief that the Guidelines are "fully consistent with binding precedent of the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit," and that, in contrast to the University's position here, "the USPTO does not find . . . *Eli Lilly* to be in conflict with binding precedent." *Id.* at 1100.

Contrary to the suggestion in the petition (Pet. 19), the *amicus* brief of the United States in *Enzo Biochem* does not contradict the PTO's Guidelines or the decision below. The government's *Enzo Biochem* brief expressly endorses both

the PTO's Guidelines and the Federal Circuit's written description requirement. *See* Brief of *amicus curiae* United States in *Enzo Biochem*, No. 01-1230, at 4, 8-9 (Fed. Cir. July 2, 2002). Indeed, the brief explicitly states that "[e]ven if a written description provides the 'manner and process of making and using' the invention, a description of the invention itself is still necessary to enable others to make and use it." *Id.* at 5. This brief thus provides no support for certiorari on the question presented here.

It is true, of course, that in *Enzo Biochem*, the government did seek en banc clarification — not of the existence of the independent written description requirement at issue here — of the precise contours of the written description requirement as applied to patents that refer to "the placement of biological matter in public depositories," *id.* at 2, an issue that the government believed could "put[] at risk numerous biological patents that rely on a reference to a deposit to help meet section 112," *id.* at 4. But that question is not presented by the petition here. Moreover, the panel decision to which the government was responding, 285 F.3d 1013 (Fed. Cir. 2002), was subsequently vacated, and the subsequent panel decision, 323 F.3d 956 (Fed. Cir. 2002), expressly adopted the PTO's position regarding biological deposits and endorsed the written description guidelines. *See id.* at 964. Indeed, the irrelevance of the issues discussed in the government's *Enzo Biochem* brief to this case is confirmed by the fact that Judge Dyk dissented from the first panel decision in that case, *see* 285 F.3d at 1024-28 (Dyk, J., dissenting), yet expressly agreed with the rule of decision and outcome in this case, noting that "[i]n this particular case the failure to satisfy [the written description requirement] was not even a close case." Pet. App. 122a.

4. For similar reasons, the petition also errs in its reliance (Pet. 10, 16) on some Federal Circuit judges' concern about a related but separate issue — namely, what is necessary to satisfy the independent written description requirement in

various contexts. Specifically, just as Judge Dyk and the United States noted uncertainty in *Enzo Biochem* over the precise contours of the written description requirement in the factual context of patents referring to deposited biological materials (but did so without questioning the *existence* of such a requirement separate from enablement, Pet. App. 122a), several other judges have expressed a desire to clarify the scope of the written description requirement in other contexts. *See, e.g.*, *Housey Pharms., Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1357 (Fed. Cir. 2004) (Newman, J., dissenting); *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 1002-05 (Fed. Cir. 2000) (Lourie, J., dissenting); *SunTiger v. Scientific Research Funding Group*, 189 F.3d 1327, 1337-38 (Fed. Cir. 1999) (Lourie, J., dissenting). The opinion of Judge Newman below is another such example: While having no doubt that the question presented in the petition was correctly decided by the panel (since the written description requirement is "well-established and heretofore unchallenged"), Pet. App. 71a, Judge Newman nonetheless noted that "[t]he new biology has indeed raised new and important questions, with implications for policy as well as law." Pet. App. 72a. Judge Dyk shared this concern, and wrote separately to emphasize that the Federal Circuit had "yet to articulate satisfactory standards that can be applied to all technologies." Pet. App. 122a. But, as Judge Dyk nonetheless concluded, this case did not present the appropriate vehicle to resolve such questions, because "[i]n this particular case the failure to satisfy [the written description requirement] was not even a close case. The appellant simply did not invent, much less describe, what was claimed." Pet. App. 122a. For the same reason, this Court could not effectively use this case to address such issues; indeed, the question presented by the petition is limited to *whether* an independent written description requirement exists and does not cover *what* the proper contours of such a requirement are. Thus, the petition's

references to these other, distinct issues are just obfuscating rather than illuminating.

II. PRUDENTIAL CONCERNS COUNSEL AGAINST USING THIS PETITION TO RESOLVE THE QUESTION PRESENTED.

Not only does the petition fail to present an important question of federal law about which courts are in conflict, it also presents a poor vehicle for deciding the question that it does present. Prudential concerns thus also counsel against granting this petition.

1. A case ordinarily presents a poor vehicle to use for resolving a question presented when there are alternative grounds for the decision below that would produce the same result "in any event." *The Monrosa v. Carbon Black Export, Inc.*, 359 U.S. 180, 183 (1959). "While this Court decides questions of public importance, it decides them in the context of meaningful litigation." *Id.* at 184; *see also, e.g.*, *Springfield v. Kibbe*, 480 U.S. 257 (1987) (per curiam) (dismissing certiorari where issue did not concretely affect case); *Rescue Army v. Municipal Court*, 331 U.S. 549, 575 (1947) (declining review of question presented "in highly abstract form"). Thus, the existence of separate grounds for the same result no matter which way the question presented is decided in this Court supports a decision to "await a day when the issue is posed less abstractly." *The Monrosa*, 359 U.S. at 184. A case is also a poor vehicle for deciding a question if the issue is not squarely presented under its facts. *See, e.g.*, *Belcher v. Stengel*, 429 U.S. 118, 119 (1976) (per curiam) (dismissing certiorari because "the question framed in the petition for certiorari is not in fact presented by the record now before us"). This vehicle limitation is particularly crucial in the context of a purely "hypothetical" issue that is unlikely to arise in *other* cases. *Ticor Title Ins. Co. v. Brown*, 511 U.S. 117, 122 (1994) (per curiam).

2. This case presents a poor vehicle for resolution of the question presented for all of the foregoing reasons.

First, the outcome of the case does not depend upon the resolution of the question presented, because there are at least two alternative grounds for invalidating the '850 patent recognized below. The district court also invalidated the patent on the independent ground that it was not enabled, a requirement that petitioner repeatedly acknowledges properly exists under section 112. *E.g.*, Pet. 2, 13, 19. The Federal Circuit also expressly found the factual predicate for an enablement invalidation (although it did not need formally to reach that issue in light of its ruling on the written description requirement, Pet. App. 28a), finding that "[t]he claimed methods thus cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art." Pet. App. 23a. The panel showed that the patent did not even allow one skilled in the art to know what the invention was, much less how to make it. Pet. App. 23a-24a. Equally tellingly, even the judges who dissented from the denial of rehearing agreed that the alleged invention "was not enabled" by this patent. Pet. App. 88a.

Similarly, the panel decision indicated that there was yet another independent ground for the judgment. Section 102(f) precludes the issuance of a patent where the applicant "did not himself invent the subject matter sought to be patented." Because "[h]ere the patentee has done no more than invent a search method," the panel here observed that "it might appear that the patentee also failed to satisfy the requirements of section 102(f)." Pet. App. 30a n.10. Such an additional alternative ground for decision underscores that the petition is not the right vehicle for this Court to use to address the independent written description requirement question.

Second, the petition does not squarely present the question on facts that might illuminate its proper resolution. A proper vehicle would be one where there are findings *both* that the

written description is not satisfied *and* that the enablement requirement *is* satisfied; such a vehicle would provide the context suitable to decide the effect of the written description requirement separate from enablement. In contrast, in a case (such as this one) where there is no specific finding that the patent in question meets the enablement standard (and, indeed, the district court and the judges below have indicated that it does not), the case provides no means to disentangle the two distinct yet overlapping requirements. The issue described in the petition is thus not squarely "presented by the record" in this case in the fashion that this Court has indicated is prudentially wise and necessary for certiorari review. *Belcher*, 429 U.S. at 119.

III. THE FEDERAL CIRCUIT CORRECTLY HELD THAT SECTION 112 REQUIRES A WRITTEN DESCRIPTION OF THE INVENTION BEYOND MERELY SATISFYING THE ENABLEMENT REQUIREMENT.

In all events, the panel's decision is correct on the merits. The petition errs in suggesting otherwise.

1. Contrary to the petition, the plain language of the statute supports, rather than undermines, the Federal Circuit's judgment that section 112 requires a written description of the invention beyond merely satisfying the enablement requirement. Section 112 provides that "[t]he specification shall contain a written description" of two separate things: First, it must "contain a written description of the invention." Second, it must describe "the manner and process of making and using it." These two requirements are connected by the word "and," thus expressly mandating that *both* requirements must be satisfied. *See, e.g.*, *In re Barker*, 559 F.2d 588, 591 (CCPA 1977) (noting that a contrary reading would "render superfluous the requirement that the specification contain a written description — 'of the manner and process of making and using it [the invention],'" for "if there were a description enabling 'any person skilled in the

art . . . to make and use,' there would be no need to require a description of the 'manner and process of making and using'").

The University has no response to this basic textual point. Instead, its only textual argument is that the enablement requirement that follows the latter of these two requirements modifies both of them rather than merely the "making and using" description requirement, thus providing that both the description of the invention and the description of how to make and use it must only satisfy the enablement requirement. Pet. 18-19. This argument is in error.

In the first place, the enablement requirement directly follows the "making and using" description requirement and by its terms refers to the specificity needed in allowing a skilled artisan "to make and use" the invention. It thus relates to the language only of the second description requirement, not the requirement that the invention be described.

Even more fundamentally, the University's argument is entirely irrelevant. Even if the University were correct that both the descriptions "of the invention" *and* "of the manner and process of making and using it" are grammatically connected to the enablement requirement, that would in no way relieve the applicant of the statutory obligation to give "a written description of the invention" as well as how to make it. The enablement requirement is a further specification on what must be contained in the referenced description; it is not a repudiation of the need for a written description that actually identifies the invention being patented. Petitioner offers no reading under which it could obviate the need to satisfy the required description "of the invention" distinct from how to "make and use" it. Indeed, petitioner's construction improperly renders much of the statutory language superfluous and redundant. *See Barker*, 559 F.2d at 592 (noting that "it is presumed that Congress did not use superfluous words").

2. Petitioner similarly errs in suggesting that an independent written description requirement serves no purpose. Pet. 20-22. Among other things, that requirement has the function of "distinguish[ing the invention] from all other things before known." Patent Act of 1793 § 3, 1 Stat. 318, 321; *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 434 (1822) (noting need to prevent the inventor from "pretending that his invention is more than what it really is"). While the University argues that this function has somehow been abrogated because those words do not themselves occur in the current version of the Patent Act, Pet. 19-20, the requirement that the specification describe the invention itself, separate from the manner of making and using it, remained in the statute. And that requirement continues to serve the function of "ensur[ing] that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000); *see also, e.g.*, *In re Wright*, 866 F.2d 422, 424 (Fed. Cir. 1989) ("The specification as originally filed must convey clearly to those skilled in the art the information that the applicant has *invented* the specific subject matter later claimed." (internal quotation marks omitted; emphasis added)).

As the Federal Circuit has indicated, the written description requirement also "serves a teaching function, as a '*quid pro quo*' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" Pet. App. 12a (quoting *Enzo Biochem*, 323 F.3d at 970). The PTO has similarly stated that the written description requirement serves both to convey the information that the patentee has invented the claimed subject matter and to further public knowledge of the invention in exchange for exclusivity. *See* 66 Fed. Reg. at 1104.

3. Without a citation to the decision below, the petition also erroneously asserts that "the panel dispensed with the statutorily-required perspective of persons skilled in the art." Pet. 22. The panel did no such thing. In fact, it noted that the written description requirement must "be met in some way so as to describe the claimed invention so that one skilled in the art can recognize what is claimed." Pet. App. 14a (internal quotation marks omitted). Moreover, the panel repeatedly applied the perspective of one skilled in the art as the relevant benchmark in its discussion of the issue. *See, e.g.*, Pet. App. 19a, 23a, 28a, 29a.

4. The University's argument that the decision below disrupts settled expectations, Pet. 24-26, is equally unfounded. That argument rests upon the false premise that the panel applied "a new patentability doctrine." Pet. 24.

In fact, as shown above, the plain language of section 112, an unbroken line of Federal Circuit precedents, and the guidelines published in the Federal Register by the PTO have all put inventors and others on notice of the independent written description requirement. As Judge Newman emphasized below, settled expectations are fully in line with the panel's decision: "It has always been necessary to disclose and describe what is patented. It has never been the law that one can claim what is not made known and set forth in the patent." Pet. App. 72a. Judge Lourie made this point similarly emphatically, noting that "there is and always has been a separate written description requirement in the patent law." Pet. App. 74a; *see also* Pet. App. 75a (noting that "the interpretation of the statute as containing a separate written description requirement did not originate with *Lilly*. It has always been there." (citations omitted)).

Indeed, it is the University's position that would upset settled expectations and reliance interests. The University itself acknowledges that the doctrine they criticize has been binding law for more than three decades, and both the University and Judge Rader agree that it took on increased

vitality seven years ago in the *Eli Lilly* case. Pet. 14; Pet. App. 78a-79a. Indeed, the PTO published guidelines on the issue to ensure widespread and common understanding of the requirement. It is thus the University's request that this Court overturn over thirty years of precedent and the applicable administrative guidelines that would drastically upset settled expectations and reliance interests.

5. Finally, contrary to the petition, the written description requirement does not deprive research institutions of patent protection for their inventions or undermine the Bayh-Dole Act. Pet. 26-29. The University mischaracterizes the decision below in stating that it "preclude[s] patenting inventions founded on basic research." Pet. 27. So long as there is an actual invention that can be and is described in the specification, the decision below does nothing to prevent an invention's patentability. And, without such an invention, free-floating "basic research" has never been patentable. *See, e.g.*, *Brenner v. Manson*, 383 U.S. 519, 536 (1966) ("[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

The Bayh-Dole Act is even more clearly irrelevant. As the panel noted, Pet. App. 27a, nothing in that statute has anything to do with the requirements for patentability; rather, that statute governs relationships among the government, universities, and small businesses in the use of inventions stemming from federally funded research. 35 U.S.C. §§ 200-12.

In fact, the substantive provisions of the Bayh-Dole Act govern the ownership and licensing of "inventions," which is expressly defined to mean "any invention or discovery *which is or may be patentable* or otherwise protectable under this title." *Id.* § 201(d) (emphasis added). Thus, the covered "inventions" are expressly limited to those that meet the independent requirements for patentability, including those requirements imposed by section 112.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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